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# 4

U.S. National Stage of  
International Application No.: PCT/JP/03/03846  
International Filing Date: 27 March 2003  
Earliest Priority Date: 29 March 2002  
Applicants: Hisashi Narimatsu, Takashi Kudo and Hirko Iwasaki  
Title: NOVEL GALACTOSYLTRANSFERASES, THEIR PEPTIDES, AND  
NUCLEIC ACIDS ENCODING THE SAME  
Attorney's Docket No.: 3462.1010-000

Date: <u>5-11-05</u>
EXPRESS MAIL LABEL NO. <u>EV 214895097 US</u>

INFORMATION DISCLOSURE STATEMENT

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:  
☐ a Statement under 37 CFR 1.97(e), as checked below, or  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:  
☐ a Statement under 37 CFR 1.97(e), as checked below, and  
☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
  - ☒ Copies of the cited references are enclosed.
    - ☐ Copies of issued U.S. patents and published U.S. applications are not required and are not being provided.
  - ☐ Copies of the cited references are enclosed except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
  - ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
  - ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
    - ☐ the explanation provided on the attached sheet.
    - ☐ the explanation provided in the Specification.
    - ☐ submission of the enclosed International Search Report.
    - ☐ submission of the enclosed English-language version of a foreign Search Report and/or foreign Office Action.
    - ☐ the enclosed English language abstract.

☐ Applicant requests that the following non-published pending applications be considered:

Examiner's  
Initials

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_ U.S. Patent Application No. [ ], by [inventor(s)], filed [ ], Docket No.: [ ]

\_\_\_\_\_  
Examiner

\_\_\_\_\_  
Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed, except any application filed on or after June 30, 2003, which has been scanned into the PTO's Image File Wrapper (IFW) system and is available to the examiner.
- ☐ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. [ ], to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

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Dated: 5/11/05

PTO-1449 REPRODUCED  <b>INFORMATION DISCLOSURE STATEMENT IN AN APPLICATION</b>  May 4, 2005  (Use several sheets if necessary)	ATTORNEY DOCKET NO. 3462.1010-000		APPLICATION NO. 10/509,785	
	FIRST NAMED INVENTOR Hisashi Narimatsu		FILING DATE IA filing date: 03/27/03	
	EXAMINER		CONFIRMATION NO. 3100	GROUP

FOREIGN PATENT DOCUMENTS						
		DOCUMENT NUMBER Country Code-Number-Kind Code (if known)	DATE MM-DD-YYYY	NAME OF PATENTEE OR APPLICANT OF CITED DOCUMENT	TRANSLATION YES NO	
	B1	WO 98/56804 A1	12-17-1998	Human Genome Sciences, Inc.		
	B2	WO 99/14328 A2	03-25-1999	Genentech, Inc.		
	B3	WO 00/56891 A2	09-28-2000	Incyte Pharmaceuticals, Inc.		
	B4	WO 01/04311 A1	01-18-2001	Genentech, Inc.		
	B5	WO 01/53312 A1	07-26-2001	Hyseq, Inc.		
	B6	WO 02/22660 A2	03-21-2002	Hyseq, Inc.		

  

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)	
C1	Allen, A., et al., "Origin and structure of pathogenic IgA in IgA nephropathy," <i>Biochem. Soc. Trans.</i> , 25(2): 486-490 (1997).
C2	Allen, A., and Feehally, J., "IgA Glycosylation in IgA Nephropathy," <i>Adv. Exp. Med. Biol.</i> , 435: 175-183 (1998).
C3	Allen, A.C., et al., "Galactosylation of N- and O-linked carbohydrate moieties of IgA1 and IgG in IgA nephropathy," <i>Clin. Exp. Immunol.</i> , 100(3): 470-474 (1995).
C4	Allen, A.C., et al., "Leucocyte $\beta$ 1,3 galactosyltransferase activity in IgA nephropathy," <i>Nephrol. Dial Transplant</i> , 12(4): 701-706 (1997).
C5	Greer, M. R., et al., "The nucleotide sequence of the IgA1 hinge region in IgA nephropathy," <i>Nephrol. Dial Transplant</i> , 13(8): 1980-1983 (1998).
C6	Hiki, Y., et al., "Serum IgA Class Anti-IgA Antibody in IgA Nephropathy," <i>Nephron</i> , 59(4): 552-560 (1991).
C7	Hiki, Y., et al., "O-linked Oligosaccharide on IgA1 Hinge Region in IgA Nephropathy," <i>Contrib. Nephrol.</i> , 111: 73-84 (1995).
C8	Hiki, Y., et al., "Association of Asialo-galactosyl $\beta$ 1-3N- acetylgalactosamine on the Hinge with a Conformational Instability of Jacalin-Reactive Immunoglobulin A1 in Immunoglobulin A Nephropathy," <i>J. Am. Soc. Nephrol.</i> 7(6): 955-960 (1996).

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C9	Hiki, Y., et al., "Reactivity of Glomerular and Serum IgA1 to Jacalin in IgA Nephropathy," <i>Nephron</i> , 72(3): 429-435 (1996).	
C10	Iwase, H., et al., "Analysis of Glycoform of <i>O</i> -Glycan from Human Myeloma Immunoglobulin A1 by Gas-Phase Hydrazinolysis Following Pyridylation of Oligosaccharides," <i>Anal. Biochem.</i> , 206(1): 202-205 (1992).	
C11	Iwase, H., et al., "Estimation of the Number of <i>O</i> -linked Oligosaccharides per Heavy Chain of Human Serum IgA1 by Matrix-Assisted Laser Desorption Ionization Time-of-Flight Mass Spectrometry (MALDI-TOFMS) Analysis of the Hinge Glycopeptide," <i>J. Biochem (Tokyo)</i> , 120(2): 393-397 (1996).	
C12	Iwase, H., et al., "Abundance of Gal $\beta$ 1,3GalNAc in <i>O</i> -Linked Oligosaccharide on Hinge Region of Polymerized IgA1 and Heat-Aggregated IgA1 from Normal Human Serum," <i>J. Biochem (Tokyo)</i> , 120(1): 92-97 (1996).	
C13	Iwase, H., et al., "Application of matrix-assisted laser desorption ionization time-of-flight mass spectrometry to the analysis of glycopeptide-containing multiple <i>O</i> -Linked oligosaccharides," <i>J. Chromatogr. B. Biomed. Sci. Appl.</i> 709(1): 145-149 (1998).	
C14	Iwase, H., et al., "Study of the Relationship between Sticky Human Serum IgA1 and its <i>O</i> -Glycan Glycoform," <i>Biochem. Biophys. Res. Commun.</i> , 261(2): 472-477 (1999).	
C15	Iwase, H., et al., "Mutual separation of hinge-glycopeptide isomers bearing five <i>N</i> -acetylgalactosamine residues from normal human serum immunoglobulin A1 by capillary electrophoresis," <i>J. Chromatogr. B. Biomed. Sci. Appl.</i> , 728(2): 175-183 (1999).	
C16	Iwase, H., and Hiki, Y., "Incompleteness of Mucin-Type Sugar Chain of Human Serum IgA1 as Possible Cause of IgA Nephropathy," <i>Trends in Glycoscience and Glycotechnology</i> , 11(59): 113-118 (1999).	
C17	Iwase, H., et al., "Aggregated human serum immunoblogulin A1 induced by neuraminidase treatment had a lower number of <i>O</i> -linked sugar chains on the hinge portion," <i>J. Chromatogr. B. Biomed. Sci. Appl.</i> , 724(1): 1-7 (1999).	
C18	Ju, T., et al., "Cloning and Expression of Human Core 1 $\beta$ 1,3-Galactosyltransferase," <i>J. Biol. Chem.</i> , 277(1): 178-186 (2002).	
C19	Ju, T., et al., "Purification, Characterization, and Subunit Structure of Rat Core 1 $\beta$ 1,3-Galactosyltransferase," <i>J. Biol. Chem.</i> , 277(1): 169-177 (2002).	

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	EXAMINER	CONFIRMATION NO. 3100	GROUP	

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)		
C20	Ju., T., and Cummings, R. D., "A unique molecular chaperone Cosmc required for activity of the mammalian core 1 $\beta$ -galactosyltransferase," <i>Proc. Natl. Acad. Sci. USA</i> , 99(26): 16613-16618 (2002).	
C21	Keusch, J., et al., "B lymphocyte galactosyltransferase protein levels in normal individuals and in patients with rheumatoid arthritis," <i>Glycoconj. J.</i> , 15(11): 1093-1097 (1998).	
C22	Kudo, T., et al., "Molecular Cloning and Characterization of a Novel UDP-Gal:GalNAc $\alpha$ Peptide $\beta$ 1,3-Galactosyltransferase (C1Gal-T2), an Enzyme Synthesizing a Core 1 Structure of O-Glycan," 277(49): 47724-47731 (2002).	
C23	Kokuba, T., et al., "Protective Role of IgA1 Glycans Against IgA1 Self-Aggregation and Adhesion to Extracellular Matrix Proteins," <i>J. Am. Soc. Nephrol.</i> , 9(11): 2048-2054 (1998).	
C24	Leppänen, A., et al., "A Novel Glycosulfopeptide Binds to P-selectin and Inhibits Leukocyte Adhesion to P-selectin," <i>J. Biol. Chem.</i> , 274(35): 24838-24848 (1999).	
C25	Leung, J. C. K., et al., "Increased sialylation of polymeric immunoglobulin A <sub>1</sub> : Mechanism of selective glomerular deposition in immunoglobulin A nephropathy?," <i>J. Lab Clin. Med.</i> , 133(2): 152-160 (1999).	
C26	Mestecky, J., et al., "Defective Galactosylation and Clearance of IgA1 Molecules as a Possible Etiopathogenic Factor in IgA Nephropathy," <i>Contrib. Nephrol.</i> 104: 172-182 (1993).	
C27	Saulsbury, F. T., "Alterations in the O-Linked Glycosylation of IgA1 in Children with Henoch-Schönlein Purpura," <i>J. Rheumatol.</i> , 24(11): 2246-2249 (1997).	
C28	Tanaka, A., et al., "Evidence for a site-specific fucosylation of N-linked oligosaccharide of immunoglobulin A1 from normal human serum," <i>Glycoconj. J.</i> , 15(10): 995-1000 (1998).	
C29	Wold, A. E., et al., "Characterization of IgA1, IgA2 and Secretory IgA Carbohydrate Chains Using Plant Lectins," <i>Adv. Exp. Med. Biol.</i> , 371A: 585-589 (1995).	
C30	Zhang, W. and Lachmann, P. J., "Glycosylation of IgA is required for optimal activation of the alternative complement pathway by immune complexes," <i>Immunology</i> , 81(1): 137-141 (1994).	

EXAMINER	DATE CONSIDERED
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